MAR 1 4 2014

K140388

510(K) SUMMARY
Lumenis Ltd.

Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories - Lumenis Pulse 120H

Applicant Name:

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Contact Person:

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Date Prepared:

February 12, 2014

Trade Name:

Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories - Lumenis Pulse 120H

Classification Name:

Powered laser surgical instrument

Product Code:

GEX

Device Class:

Class II

Regulation Number:

21 CFR 878.4810

Panel:

General & Plastic Surgery

Predicate Device:

Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers And Delivery Devices And Accessories [Lumenis], Cleared under K011703

Intended Use/ Indications for Use:

The Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories - Lumenis Pulse 120H is intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery.

The Lumenis Pulse 120H System and the currently marketed VersaPulse PowerSuite Holmium Surgical Lasers with Delivery Devices and Accessories are indicated for use in the performance of specific surgical applications as follows:

<u>Urology</u>

- Endoscopic transurethral incision of the prostate (TUIP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser enucleation of the prostate (HoLEP), holmium laser resection of the prostate (HoLRP), hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy (BPH)
- Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
  - bladder;
  - superficial and invasive bladder, urethral and ureteral tumors;
  - condylomas;
  - lesions of external genitalia;
  - ureteral and penile hemangioma;
  - ureteral strictures;
  - bladder neck obstructions
- Urinary Lithotripsy including:
  - endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate stones;

- treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Arthroscopy

- Arthroscopy (ablation, excision and coagulation of soft and cartilaginous tissue) in various small and large joints of the body, excluding the spine, including:
  - meniscectomy;
  - plica removal;
  - ligament and tendon release;
  - contouring and sculpting of articular surfaces;
  - debridement of inflamed synovial tissue (synovectomy);
  - loose body debridement;
  - chondromalacia and tears;
  - lateral retinecular release;
  - capsulectomy in the knee;
  - chondroplasty in the knee;
  - chondrornalacia ablation.
- Discectorny including:
  - percutaneous vaporization of the L4-5 and L5-Sl lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

General Surgery

- Open, laparoscopic, and endoscopic general surgery (vaporization, ablation, incision, and coagulation of soft tissue) including:
  - cholecystectomy;
  - lysis of adhesions;
  - appendectomy;
  - biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon;
  - skin incision;
  - tissue dissection;
  - excision of external tumors and lesions;
  - complete or partial resection of internal organs, tumors and lesions;
  - mastectomy;
  - hepatectomy;
  - pancreatectomy;
  - splenectomy;
  - thyroidectomy;
  - parathyroidectomy;
  - herniorrhaphy;
  - tonsillectomy;
  - lymphadenectomy;

- partial nephrectomy;
- pilonidal cystectomy;
- resection of lipoma;
- debridement of decubitus ulcer;
- hemorrhoids;
- debridement of statis ulcer;
- biopsy.

ENT Surgery

- Endoscopic endonasal/ sinus surgery (ablation, vaporization, incision, and coagulation of soft tissue and cartilage) including:
  - partial turbinectomy;
  - ethmoidectomy;
  - polypectomy;
  - maxillary antrostomy;
  - frontal sinusotomy;
  - sphenoidotomy;
  - dacryocystorhinostomy (DCR);
  - functional endoscopic sinus surgery (FESS).

Gynecological Surgery

- Open and laparoscopic gynecological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue).

Gasteroenterology Surgery

- Open and endoscopic gasteroenterology surgery (ablation, vaporization, incision, excision, resection, coagulation and hemostasis, including:
  - gall bladder calculi;
  - biliary/bile duct calculi;
  - benign and malignant neoplasm;
  - polyps;
  - colitis;
  - ulcers;
  - angiodysplasia;
  - hemorrhoids;
  - varices;
  - esophagitis;
  - esophageal ulcer;
  - Mallory-Weiss tear;
  - gastric ulcer;
  - duodenal ulcer;
  - non-bleeding ulcer;
  - gastric erosions;

- colorectal cancer;
- gastritis;
- bleeding tumors;
- pancreatitis;
- vascular malformations;
- telangiectasias;
- telangiectasias of the Osler-Weber-Renu disease.

Pulmonary Surgery

- Open and endoscopic pulmonary surgery (cutting, ablation, vaporization, incision, excision and coagulation of soft tissue.

Dermatology and Plastic Surgery

- Incision, excision, resection, ablation, coagualation, hemostasis and vaporization of soft, mucosal, fatty and cartilaginous tissues, in therapeutic plastic, dennatologic and aesthetic surgical procedures, including:
  - scars;
  - tattoo removal;
  - vascular lesions;
  - port wine stains;
  - hemangioma;
  - telangiectasia of the face and leg;
  - rosacea;
  - corns;
  - papillomas;
  - basal cell carcinomas;
  - lesions of skin and subcutaneous tissue;
  - plantar warts;
  - periungual and subungual warts;
  - debridement of decubitus ulcer;
  - skin tag vaporization.

Device Description:

The Lumenis Pulse 120H System, which is the subject of this submission, is a single wavelength holmium (Ho:YAG) laser, being a new member in the VersaPulse PowerSuite family of holmium lasers manufactured by Lumenis Ltd. The subject device is a modification of the previously cleared Lumenis laser system, the VersaPulse PowerSuite 100 Watt (VPPS100, most recently cleared under K011703), also a member of the same product family. The modified subject Lumenis Pulse 120H system relies on the same fundamental underlying technology of the cited predicate system, as well as of all Lumenis holmium lasers used in clinical practice. The subject device modifications involve both hardware (HW) and software (SW) elements, whereas the functional

capabilities of the laser system remain unaltered in both the modified and cleared systems. The Lumenis Pulse 120H additionally includes an integrated suction pump in order to increase user convenience in procedures where aspiration of surgical debris is common practice, which represents a minor subject product change in relation to the predicate.

The subject Lumenis Pulse 120H system is a solid state Single Wavelength (Holmium) surgical laser, being comprised of the following functional HW components:

- Laser Console
- Dual pedal Footswitch
- Variety of Fiber Optic Delivery Devices (fibers) and accessories

The Lumenis Pulse 120H system is operated and controlled via proprietary SW. The SW comprises embedded SW in the main and peripheral processors, and Graphical User Interface (GUI) application running on a Personnel Computer (PC).

Substantial Equivalence

The intended use and indications for use of the Lumenis Pulse 120H are identical to the intended use and indications for use of its predicate device. In addition, the same technological characteristics and principles of operation apply for both systems. The modifications introduced to the subject Lumenis Pulse 120H system as compared to the predicate system are designed and intended mainly for system modernization and increased user convenience in accordance with market/design inputs.

Performance testing was conducted in order to demonstrate the performance of the Lumenis Pulse 120H and to verify that no new questions of safety and effectiveness have been raised due to the modifications introduction. The following performance activities were performed:

- Risk analysis
- Electrical and laser safety and electromagnetic compatibility testing
- Software verification and validation
- Ability of the subject system to withstand variant operation, storage and transportation conditions
- System testing (*e.g.,* footswitch, emission indicator, emergency button, ON/OFF button)

Test results indicated that the subject Lumenis Pulse 120H performs in accordance with its requirements and specifications, in similarity to its predicate device. Consequently, it is Lumenis belief that the Lumenis Pulse 120H is as safe and effective for its intended

use as its predicate and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

Lumenis Ltd.
% Merav Yarmus, Ph.D.
BioMedical Strategy (2004) Ltd.
155 Bialik Street
Ramat Gan, 5252346, Israel

Re: K140388
Trade/Device Name: Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories - Lumenis Pulse 120H
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 12, 2014
Received: February 14, 2014

Dear Dr. Yarmus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140388

Device Name
Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories - Lumenis Pulse 120H

Indications for Use *(Describe)*
The Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) Surgical Lasers and Delivery Devices and Accessories - Lumenis Pulse 120H is intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology; urinary lithotripsy; arthroscopy; discectomy; E.N.T. surgery; gynecological surgery; pulmonary surgery; gastroenterology surgery; dermatology and plastic surgery and general surgery. The Lumenis Pulse 120H System and the currently marketed VersaPulse PowerSuite Holmium Surgical Lasers with Delivery Devices and Accessories are indicated for use in the performance of specific surgical applications as follows:

Urology
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• Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
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o lesions of external genitalia;
o ureteral and penile hemangioma;
o ureteral strictures;
o bladder neck obstructions
• Urinary Lithotripsy including:
o endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate stones;
o treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Arthroscopy
• Arthroscopy (ablation, excision and coagulation of soft and cartilaginous tissue) in various small and large joints of the body, excluding the spine, including:
o meniscectomy;
o plica removal;
o ligament and tendon release;
o contouring and sculpting of articular surfaces;
o debridement of inflamed synovial tissue (synovectomy);
o loose body debridement;
o chondromalacia and tears;
o lateral retinecular release;
o capsulectomy in the knee;
o chondroplasty in the knee;
o chondromalacia ablation.
• Discectomy including:
o percutaneous vaporization of the L4-5 and L5-SI lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

General Surgery
• Open, laparoscopic, and endoscopic general surgery (vaporization, ablation, incision, and coagulation of soft tissue) including:
o cholecystectomy;
o lysis of adhesions;
o appendectomy;
o biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon;
o skin incision;
o tissue dissection;
o excision of external tumors and lesions;
o complete or partial resection of internal organs, tumors and lesions;
o mastectomy;
o hepatectomy;
o pancreatectomy;
o splenectomy;
o thyroidectomy;
o parathyroidectomy;
o herniorrhaphy;
o tonsillectomy;
o lymphadenectomy;
o partial nephrectomy;
o pilonidal cystectomy;
o resection of lipoma;
o debridement of decubitus ulcer;
o hemorrhoids;
o debridement of statis ulcer;
o biopsy.

ENT Surgery
• Endoscopic endonasal/ sinus surgery (ablation, vaporization, incision, and coagulation of soft tissue and cartilage) including:
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o gall bladder calculi;
o biliary /bile duct calculi;
o benign and malignant neoplasm;
o polyps;
o colitis;
o ulcers;
o angiodysplasia;
o hemorrhoids;

o varices;
o esophagitis;
o esophageal ulcer;
o Mallory-Weiss tear;
o gastric ulcer;
o duodenal ulcer;
o non-bleeding ulcer;
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o colorectal cancer;
o gastritis;
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• Open and endoscopic pulmonary surgery (cutting, ablation, vaporization, incision, excision and coagulation of soft tissue.

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o scars;
o tattoo removal;
o vascular lesions;
o port wine stains;
o hemangioma;
o telangiectasia of the face and leg;
o rosacea;
o corns;
o papillomas;
o basal cell carcinomas;
o lesions of skin and subcutaneous tissue;
o plantar warts;
o periungual and subungual warts;
o debridement of decubitus ulcer;
o skin tag vaporization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.03.14 10:01:22 -04'00'